

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP04-0397-00	FOR FURTHER ACTION		See Form PCT/ISA/416
International application No. PCT/JP2004/016104	International filing date (day/month/year) 29.10.2004	Priority date (day/month/year) 31.10.2003	
International Patent Classification (IPC) or national classification and IPC C12N15/09, C12N15/31, C12N15/63, C12P7/02, C12P13/00			
Applicant DAIICHI FINE CHEMICAL CO., LTD.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

- a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
- ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.15 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))

1 _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 602 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

CORRECTED
VERSION

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPER/OP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of these sheets may be marked "superceded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

The inventions as set forth in claims 1 to 38 are common to each other in relating to a plasmid originating in a microorganism belonging to the genus *Rhodococcus* and its partial fragment. As reported in Appl. Microbiol. Biotechnol., 2003, July, Vol. 62, pages 61-68, however, a plasmid originating in a microorganism belonging to the genus *Rhodococcus* and its partial fragment are known. Thus, the matter common to the inventions as set forth in claims 1 to 38 cannot be considered as a special technical feature. Accordingly, it appears that there is no technical relationship among the inventions as set forth in claims 1 to 38 involving any special technical feature and these groups of inventions cannot be considered as being so linked as to form a single general inventive concept. Such being the case, the inventions claimed in the present case have three groups of inventions, i.e.

(continued in Supplemental Box)

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-38	YES
	Claims		NO
Inventive step (IS)	Claims	1-38	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-38	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Document 1: Microbiology, 1997, Vol. 143, pages 3137 to 3147			
Document 2: Appl. Microbiol. Biotechnol., July 2003, Vol. 62, No. 1, pages 61 to 68			
Document 3: WO 2002/70714 A1 (Daiichi Fine Chemical Co., Ltd.), 12 September 2002 & EP 1371731 A1 & AU 2002234942 A1			
<u>Claims 1 to 38</u>			
The inventions set forth in claims 1 to 38 are novel and involve an inventive step in relation to documents 1 to 3 cited in the international search report.			
None of the documents sets forth the specific plasmids of <i>Rhodococcus</i> origin or fragments thereof as described in this application, and said invention would not be obvious to a person skilled in the art.			

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, Item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

(1) The inventions relating to a plasmid pRET1100 and its fragment as set forth in claims 1 to 11 and the parts relating to the fragment of the plasmid pRET1100 in claims 17, 24 and 27 to 38;

(2) The inventions relating to a plasmid pRET1000 and its fragment as set forth in claims 12 to 16 and 18 to 23 and the parts relating to the fragment of the plasmid pRET1000 in claims 17, 24 and 27 to 38; and

(3) The inventions relating to a DNA fragment represented by SEQ ID NO: 77 as set forth in claims 25 to 26 and the part relating to claims 25 to 26 in claims 27 to 38.